1	PHARMACY PRACTICE ACT AMENDMENTS
2	2020 GENERAL SESSION
3	STATE OF UTAH
4	Chief Sponsor: Evan J. Vickers
5	House Sponsor: Suzanne Harrison
6 7	LONG TITLE
8	General Description:
9	This bill amends provisions relating to the practice of pharmacy.
10	Highlighted Provisions:
11	This bill:
12	amends definitions;
13	 authorizes the dispensing of epinephrine auto-injectors and stock albuterol under
14	certain circumstances;
15	amends provisions related to out-of-state mail service pharmacies;
16	 amends provisions related to a prescription drug or device that is not readily
17	available in all pharmacies;
18	 authorizes the dispensing of a quantity or dosage form different from a prescription
19	in certain instances;
20	amends provisions related to the dispensing of a substitute for albuterol;
21	amends provisions relating to emergency refills;
22	 authorizes the dispensing of certain prescription medical devices under certain
23	circumstances;
24	 authorizes certain physicians to issue a standing prescription drug order for an
25	epinephrine auto-injector or stock albuterol in accordance with a protocol that meets
26	certain requirements;
27	 exempts a physician from liability for civil damages for acts or omissions resulting
28	from the dispensing of an epinephrine auto-injector or stock albuterol under the
29	physician's standing prescription drug order;

30	 exempts controlled substances dispensed for administration or use in a health care
31	facility outpatient setting from reporting to the state's controlled substance database;
32	and
33	 makes technical and conforming changes.
34	Money Appropriated in this Bill:
35	None
36	Other Special Clauses:
37	This bill provides a special effective date.
38	Utah Code Sections Affected:
39	AMENDS:
40	26-41-102 (Effective 07/01/20), as last amended by Laws of Utah 2019, Chapter 236
41	26-41-105 (Effective 07/01/20), as last amended by Laws of Utah 2019, Chapter 236
42	31A-46-102, as enacted by Laws of Utah 2019, Chapter 241
43	58-17b-605, as last amended by Laws of Utah 2013, Chapter 423
44	58-37f-201, as last amended by Laws of Utah 2016, Chapter 99
45	58-37f-203, as last amended by Laws of Utah 2019, Chapter 59
46	ENACTS:
47	58-17b-602.1, Utah Code Annotated 1953
48	58-17b-610.8 , Utah Code Annotated 1953
49	58-17b-1001, Utah Code Annotated 1953
50	58-17b-1002, Utah Code Annotated 1953
51	58-17b-1003, Utah Code Annotated 1953
52	58-17b-1004, Utah Code Annotated 1953
53	58-17b-1005, Utah Code Annotated 1953
54	58-17b-1006, Utah Code Annotated 1953
55	58-17b-1007, Utah Code Annotated 1953
56	RENUMBERS AND AMENDS:
57	31A-46-305, (Renumbered from 58-17b-619, as enacted by Laws of Utah 2004,

Chapter 280)
REPEALS AND REENACTS:
58-17b-608, as enacted by Laws of Utah 2004, Chapter 280
Be it enacted by the Legislature of the state of Utah:
Section 1. Section 26-41-102 (Effective 07/01/20) is amended to read:
26-41-102 (Effective 07/01/20). Definitions.
As used in this chapter:
(1) "Anaphylaxis" means a potentially life-threatening hypersensitivity to a substance.
(a) Symptoms of anaphylaxis may include shortness of breath, wheezing, difficulty
breathing, difficulty talking or swallowing, hives, itching, swelling, shock, or asthma.
(b) Causes of anaphylaxis may include insect sting, food allergy, drug reaction, and
exercise.
(2) "Asthma action plan" means a written plan:
(a) developed with a school nurse, a student's parent or guardian, and the student's
health care provider to help control the student's asthma; and
(b) signed by the student's:
(i) parent or guardian; and
(ii) health care provider.
(3) "Asthma emergency" means an episode of respiratory distress that may include
symptoms such as wheezing, shortness of breath, coughing, chest tightness, or breathing
difficulty.
(4) "Epinephrine auto-injector" means a portable, disposable drug delivery device that
contains a measured, single dose of epinephrine that is used to treat a person suffering a
potentially fatal anaphylactic reaction.
(5) "Health care provider" means an individual who is licensed as:
(a) a physician under Title 58, Chapter 67, Utah Medical Practice Act;
(b) a physician under Title 58. Chapter 68. Utah Osteopathic Medical Practice Act:

86	(c) an advanced practice registered nurse under Section 58-31b-302; or
87	(d) a physician assistant under Title 58, Chapter 70a, Utah Physician Assistant Act.
88	(6) "Pharmacist" means the same as that term is defined in Section 58-17b-102.
89	(7) "Pharmacy intern" means the same as that term is defined in Section 58-17b-102.
90	(8) "Physician" means the same as that term is defined in Section 58-67-102.
91	[(6)] (9) "Qualified adult" means a person who:
92	(a) is 18 years of age or older; and
93	(b) (i) for purposes of administering an epinephrine auto-injector, has successfully
94	completed the training program established in Section 26-41-104; and
95	(ii) for purposes of administering stock albuterol, has successfully completed the
96	training program established in Section 26-41-104.1.
97	[(7)] (10) "Qualified epinephrine auto-injector entity":
98	(a) means a facility or organization that employs, contracts with, or has a similar
99	relationship with a qualified adult who is likely to have contact with another person who may
100	experience anaphylaxis; and
101	(b) includes:
102	(i) recreation camps;
103	(ii) an education facility, school, or university;
104	(iii) a day care facility;
105	(iv) youth sports leagues;
106	(v) amusement parks;
107	(vi) food establishments;
108	(vii) places of employment; and
109	(viii) recreation areas.
110	[(8)] (11) "Qualified stock albuterol entity" means a public or private school that
111	employs, contracts with, or has a similar relationship with a qualified adult who is likely to
112	have contact with another person who may experience an asthma emergency.
113	[(9)] (12) "Stock albuterol" means a prescription inhaled medication:

114	(a) used to treat asthma; and
115	(b) that may be delivered through a device, including:
116	(i) an inhaler; or
117	(ii) a nebulizer with a mouthpiece or mask.
118	Section 2. Section 26-41-105 (Effective 07/01/20) is amended to read:
119	26-41-105 (Effective 07/01/20). Authority to obtain and use an epinephrine
120	auto-injector or stock albuterol.
121	(1) A qualified adult who is a teacher or other school employee at a public or private
122	primary or secondary school in the state, or a school nurse, may obtain from the school district
123	physician, the medical director of the local health department, or the local emergency medical
124	services director a prescription for:
125	(a) epinephrine auto-injectors for use in accordance with this chapter; or
126	(b) stock albuterol for use in accordance with this chapter.
127	[(2) A qualified adult may obtain from a physician, pharmacist, or any other person or
128	entity authorized to prescribe or dispense prescription drugs, a prescription for an epinephrine
129	auto-injector or stock albuterol.]
130	(2) (a) A qualified adult may obtain an epinephrine auto-injector for use in accordance
131	with this chapter that is dispensed by:
132	(i) a pharmacist as provided under Section 58-17b-1004; or
133	(ii) a pharmacy intern as provided under Section 58-17b-1004.
134	(b) A qualified adult may obtain stock albuterol for use in accordance with this chapter
135	that is dispensed by:
136	(i) a pharmacist as provided under Section 58-17b-1004; or
137	(ii) a pharmacy intern as provided under Section 58-17b-1004.
138	(3) A qualified adult:
139	(a) may immediately administer an epinephrine auto-injector to a person exhibiting
140	potentially life-threatening symptoms of anaphylaxis when a physician is not immediately
141	available; and

142	(b) shall initiate emergency medical services or other appropriate medical follow-up in
143	accordance with the training materials retained under Section 26-41-104 after administering an
144	epinephrine auto-injector.
145	(4) If a school nurse is not immediately available, a qualified adult:
146	(a) may immediately administer stock albuterol to an individual who:
147	(i) has a diagnosis of asthma by a health care provider;
148	(ii) has a current asthma action plan on file with the school; and
149	(iii) is showing symptoms of an asthma emergency as described in the student's asthma
150	action plan; and
151	(b) shall initiate appropriate medical follow-up in accordance with the training
152	materials retained under Section 26-41-104.1 after administering stock albuterol.
153	(5) (a) A qualified entity that complies with Subsection (5)(b) or (c), may obtain [from
154	a physician, pharmacist, or any other person authorized to prescribe or dispense prescription
155	drugs, a prescription for] a supply of epinephrine auto-injectors or stock albuterol, respectively,
156	from a pharmacist under Section 58-17b-1004, or a pharmacy intern under Section
157	<u>58-17b-1004</u> for:
158	(i) storing:
159	(A) the epinephrine auto-injectors on the qualified epinephrine auto-injector entity's
160	premises; and
161	(B) stock albuterol on the qualified stock albuterol entity's premises; and
162	(ii) use by a qualified adult in accordance with Subsection (3) or (4).
163	(b) A qualified epinephrine auto-injector entity shall:
164	(i) designate an individual to complete an initial and annual refresher training program
165	regarding the proper storage and emergency use of an epinephrine auto-injector available to a
166	qualified adult; and
167	(ii) store epinephrine auto-injectors in accordance with the standards established by the
168	department in Section 26-41-107.
169	(c) A qualified stock albuterol entity shall:

170	(i) designate an individual to complete an initial and annual refresher training program
171	regarding the proper storage and emergency use of stock albuterol available to a qualified
172	adult; and
173	(ii) store stock albuterol in accordance with the standards established by the department
174	in Section 26-41-107.
175	Section 3. Section 31A-46-102 is amended to read:
176	31A-46-102. Definitions.
177	As used in this chapter:
178	(1) "Administrative fee" means any payment, other than a rebate, that a pharmaceutical
179	manufacturer makes directly or indirectly to a pharmacy benefit manager.
180	(2) "Contracting insurer" means an insurer as defined in Section 31A-22-636 with
181	whom a pharmacy benefit manager contracts to provide a pharmacy benefit management
182	service.
183	(3) "Device" means the same as that term is defined in Section 58-17b-102.
184	$[\frac{3}{2}]$ (4) "Pharmacist" means the same as that term is defined in Section 58-17b-102.
185	$\left[\frac{4}{5}\right]$ "Pharmacy" means the same as that term is defined in Section 58-17b-102.
186	[(5)] (6) "Pharmacy benefits management service" means any of the following services
187	provided to a health benefit plan, or to a participant of a health benefit plan:
188	(a) negotiating the amount to be paid by a health benefit plan for a prescription drug; or
189	(b) administering or managing a prescription drug benefit provided by the health
190	benefit plan for the benefit of a participant of the health benefit plan, including administering
191	or managing:
192	(i) a mail service pharmacy;
193	(ii) a specialty pharmacy;
194	(iii) claims processing;
195	(iv) payment of a claim;
196	(v) retail network management;
197	(vi) clinical formulary development;

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198	(vii) clinical formulary management services;
199	(viii) rebate contracting;
200	(ix) rebate administration;
201	(x) a participant compliance program;
202	(xi) a therapeutic intervention program;
203	(xii) a disease management program; or
204	(xiii) a service that is similar to, or related to, a service described in Subsection [(5)]
205	$\underline{(6)}(a)$ or $\underline{(5)}$ $\underline{(6)}(b)(i)$ through (xii).
206	[(6)] (7) "Pharmacy benefit manager" means a person licensed under this chapter to
207	provide a pharmacy benefits management service.
208	[(7)] (8) "Pharmacy service" means a product, good, or service provided to an
209	individual by a pharmacy or pharmacist.
210	[(8)] (9) (a) "Rebate" means a refund, discount, or other price concession that is paid
211	by a pharmaceutical manufacturer to a pharmacy benefit manager based on a prescription
212	drug's utilization or effectiveness.
213	(b) "Rebate" does not include an administrative fee.
214	Section 4. Section 31A-46-305, which is renumbered from Section 58-17b-619 is
215	renumbered and amended to read:
216	[58-17b-619]. <u>31A-46-305.</u> Out-of-state mail service pharmacies Drugs
217	not readily available in all pharmacies.
218	(1) As used in this section, "out-of-state mail service pharmacy" means the same as that
219	term is defined in Section 58-17b-102.
220	[(1) Any] (2) Except as provided in Subsection (3), a third party payor [for] of
221	pharmaceutical services within the state, or its agent or contractor, may not require [any] a
222	pharmacy patient to obtain prescription drug benefits from [a specific] one or more out-of-state
223	[pharmacy] mail service pharmacies as a condition of obtaining third party payment
224	prescription drug benefit coverage as defined in rule.
225	[(2) (a) This section does not prohibit any third party payor of pharmaceutical services,

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who provides for reimbursement to the pharmacy patient or payment on his behalf, from exercising the right to limit the amount reimbursed for the cost of prescription drugs based upon the cost of identical prescription drugs available through a designated out-of-state pharmacy.] [(b) Notwithstanding Subsection (2)(a), any third party payor of pharmaceutical services may restrict the type of outlet where a patient may obtain certain prescriptive drugs and devices, such as injectable medications, that are not readily available in all pharmacies. The payor may also restrict access to no more than one mail-order pharmacy. [(3) Each third party payor of pharmaceutical services shall identify as a part of the third party agreement or contract the designated out-of-state pharmacy which shall be used as the base line comparison. (3) For a prescription drug or device that is not readily available in all pharmacies, including an injectable medication, a third party payor of pharmaceutical services may require a pharmacy patient to obtain prescription drug benefits from certain pharmacies, including one or more out-of-state mail service pharmacies. (4) (a) A violation of this section is a class A misdemeanor. (b) Each violation of this section is a separate offense. Section 5. Section **58-17b-602.1** is enacted to read: 58-17b-602.1. Dispensing quantity or dosage form different from prescription. (1) Without specific authorization from a prescriber, a pharmacist or pharmacy intern may dispense: (a) a prescription in a quantity different than the quantity prescribed if the prescribed quantity or package size is not commercially available; and (b) a prescription in a dosage form different than the dosage form prescribed, if in the professional judgement of the pharmacist or pharmacy intern, dispensing a different dosage form is in the best interest of the patient. (2) This section does not apply if: (a) the substitute would change the bioavailability of the medication;

254	(b) the substitute would change the treatment parameters; or
255	(c) the prescriber has written or clearly designated "dispense as written" on the
256	prescription.
257	Section 6. Section 58-17b-605 is amended to read:
258	58-17b-605. Drug product equivalents.
259	(1) For the purposes of this section:
260	(a) (i) "Drug" is as defined in Section 58-17b-102.
261	(ii) "Drug" does not mean a "biological product" as defined in Section 58-17b-605.5.
262	(b) "Drug product equivalent" means:
263	(i) a drug product that is designated as the therapeutic equivalent of another drug
264	product in the Approved Drug Products with Therapeutic Equivalence Evaluations prepared by
265	the Center for Drug Evaluation and Research of the United States Food and Drug
266	Administration[-]; and
267	(ii) notwithstanding Subsection (1)(b)(i), an appropriate substitute for albuterol
268	designated by division rule made under Subsection (9).
269	(2) A pharmacist or pharmacy intern dispensing a prescription order for a specific drug
270	by brand or proprietary name may substitute a drug product equivalent for the prescribed drug
271	only if:
272	(a) the purchaser specifically requests or consents to the substitution of a drug product
273	equivalent;
274	(b) the drug product equivalent is of the same generic type and is designated the
275	therapeutic equivalent in the approved drug products with therapeutic equivalence evaluations
276	prepared by the Center for Drug Evaluation and Research of the Federal Food and Drug
277	Administration;
278	(c) the drug product equivalent is permitted to move in interstate commerce;
279	(d) the pharmacist or pharmacy intern counsels the patient on the use and the expected
280	response to the prescribed drug, whether a substitute or not, and the substitution is not
281	otherwise prohibited by this chapter;

(e) the prescribing practitioner has not indicated that a drug product equivalent may not be substituted for the drug, as provided in Subsection (6); and

(f) the substitution is not otherwise prohibited by law.

- (3) (a) Each out-of-state mail service pharmacy dispensing a drug product equivalent as a substitute for another drug into this state shall notify the patient of the substitution either by telephone or in writing.
- (b) Each out-of-state mail service pharmacy shall comply with the requirements of this chapter with respect to a drug product equivalent substituted for another drug, including labeling and record keeping.
- (4) Pharmacists or pharmacy interns may not substitute without the prescriber's authorization on trade name drug product prescriptions unless the product is currently categorized in the approved drug products with therapeutic equivalence evaluations prepared by the Center for Drug Evaluation and Research of the Federal Food and Drug Administration as a drug product considered to be therapeutically equivalent to another drug product.
- (5) A pharmacist or pharmacy intern who dispenses a prescription with a drug product equivalent under this section assumes no greater liability than would be incurred had the pharmacist or pharmacy intern dispensed the prescription with the drug product prescribed.
- (6) (a) If, in the opinion of the prescribing practitioner, it is in the best interest of the patient that a drug product equivalent not be substituted for a prescribed drug, the practitioner may indicate a prohibition on substitution either by writing "dispense as written" or signing in the appropriate space where two lines have been preprinted on a prescription order and captioned "dispense as written" or "substitution permitted".
- (b) If the prescription is communicated orally by the prescribing practitioner to the pharmacist or pharmacy intern, the practitioner shall indicate the prohibition on substitution and that indication shall be noted in writing by the pharmacist or pharmacy intern with the name of the practitioner and the words "orally by" and the initials of the pharmacist or pharmacy intern written after it.
 - (7) A pharmacist or pharmacy intern who substitutes a drug product equivalent for a

310	prescribed drug shall communicate the substitution to the purchaser. The drug product
311	equivalent container shall be labeled with the name of the drug dispensed, and the pharmacist,
312	pharmacy intern, or pharmacy technician shall indicate on the file copy of the prescription both
313	the name of the prescribed drug and the name of the drug product equivalent dispensed in its
314	place.
315	(8) (a) For purposes of this Subsection (8), "substitutes" means to substitute:
316	(i) a generic drug for another generic drug;
317	(ii) a generic drug for a nongeneric drug;
318	(iii) a nongeneric drug for another nongeneric drug; or
319	(iv) a nongeneric drug for a generic drug.
320	(b) A prescribing practitioner who makes a finding under Subsection (6)(a) for a
321	patient with a seizure disorder shall indicate a prohibition on substitution of a drug product
322	equivalent in the manner provided in Subsection (6)(a) or (b).
323	(c) Except as provided in Subsection (8)(d), a pharmacist or pharmacy intern who
324	cannot dispense the prescribed drug as written, and who needs to substitute a drug product
325	equivalent for the drug prescribed to the patient to treat or prevent seizures shall notify the
326	prescribing practitioner prior to the substitution.
327	(d) Notification under Subsection (8)(c) is not required if the drug product equivalent is
328	paid for in whole or in part by Medicaid.
329	(9) (a) The division shall designate by rule made in accordance with Title 63G, Chapter
330	3, Utah Administrative Rulemaking Act, and in consultation with the board, the Physicians
331	Licensing Board created in Section 58-67-201, and the Osteopathic Physician and Surgeon's
332	<u>Licensing Board created in Section 58-68-201</u> , appropriate substitutes for albuterol.
333	(b) Subsections (2)(b) and (4) do not apply to the substitution of a drug product
334	equivalent for albuterol.
335	[9] (10) Failure of a licensed medical practitioner to specify that no substitution is
336	authorized does not constitute evidence of negligence.

Section 7. Section **58-17b-608** is repealed and reenacted to read:

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338	58-17b-608. Emergency refills.
339	(1) If a prescription may not be refilled otherwise, a pharmacist or pharmacy intern
340	may refill the prescription in an emergency without the prescribing practitioner's authorization
341	<u>if:</u>
342	(a) the prescription is for a drug that is not a controlled substance;
343	(b) the patient is currently using the drug prescribed;
344	(c) the prescribing practitioner is not available promptly to authorize the refill;
345	(d) the pharmacist or pharmacy intern, or another pharmacist or pharmacy intern at the
346	same pharmacy, has not previously dispensed a refill for the prescription under this section;
347	(e) refilling the prescription is in the interest of the patient's health;
348	(f) in the professional judgment of the pharmacist or pharmacy intern the prescription
349	should be refilled;
350	(g) except as provided in Subsection (1)(h), the pharmacist or pharmacy intern
351	dispenses the medication in accordance with the prescribing practitioner's instructions included
352	with the prescription; and
353	(h) the pharmacist or pharmacy intern dispenses no more than the amount necessary to
354	address the emergency.
355	(2) If the prescription for a drug dispensed under Subsection (1) is on file with the
356	pharmacy where the drug is dispensed, the pharmacist or pharmacy intern may dispense more
357	than a three-day supply only if:
358	(a) (i) the prescription has expired within the past 30 days; or
359	(ii) no refills are remaining on the prescription; and
360	(b) the amount dispensed does not exceed the lesser of:
361	(i) a 30-day supply; or
362	(ii) the quantity last dispensed at the pharmacy pursuant to the prescription as either a
363	fill or a refill.
364	(3) A pharmacist or pharmacy intern who dispenses a prescription refill under this
365	section shall inform the prescribing practitioner of the emergency refill as soon as practicable.

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366	Section 8. Section 58-17b-610.8 is enacted to read:
367	58-17b-610.8. Prescription devices.
368	(1) The following documents from a prescribing practitioner shall be considered a
369	prescription for purposes of dispensing of and payment for a device described in Subsection
370	(3), if the device is prescribed or indicated by the document and the document is on file with a
371	pharmacy:
372	(a) a written prescription; or
373	(b) a written record of a patient's:
374	(i) current diagnosis; or
375	(ii) treatment protocol.
376	(2) A pharmacist or pharmacy intern at a pharmacy at which a document that is
377	considered a prescription under Subsection (1) is on file may dispense a prescription device
378	described in Subsection (3) to the patient in accordance with:
379	(a) the document that is considered a prescription under Subsection (1); and
380	(b) rules made by the division under Subsection (4).
381	(3) This section applies to:
382	(a) nebulizers;
383	(b) spacers for use with nebulizers or inhalers; and
384	(c) diabetic testing supplies.
385	(4) The division shall make rules in accordance with Title 63G, Chapter 3, Utah
386	Administrative Rulemaking Act, and in consultation with the board, the Physicians Licensing
387	Board created in Section 58-67-201, and the Osteopathic Physician and Surgeon's Licensing
388	Board created in Section 58-68-201, to implement this section.
389	Section 9. Section 58-17b-1001 is enacted to read:
390	Part 10. Epinephrine Auto-Injector and Stock Albuterol Act
391	58-17b-1001. Title.
392	This part is known as the "Epinephrine Auto-Injector and Stock Albuterol Act."
393	Section 10. Section 58-17b-1002 is enacted to read:

394	<u>58-17b-1002.</u> Definitions.
395	As used in this part:
396	(1) "Epinephrine auto-injector" means the same as that term is defined in Section
397	<u>26-41-102.</u>
398	(2) "Local health department" means the same as that term is defined in Section
399	<u>26A-1-102.</u>
400	(3) "Physician" means the same as that term is defined in Section 58-67-102.
401	(4) "Qualified adult" means the same as that term is defined in Section 26-41-102.
402	(5) "Qualified epinephrine auto-injector entity" means the same as that term is defined
403	in Section 26-41-102.
404	(6) "Qualified stock albuterol entity" means the same as that term is defined in Section
405	<u>26-41-102.</u>
406	(7) "Stock albuterol" means the same as that term is defined in Section 26-41-102.
407	Section 11. Section 58-17b-1003 is enacted to read:
408	58-17b-1003. Voluntary participation.
409	This part does not create a duty or standard of care for a person to prescribe or dispense
410	an epinephrine auto-injector or stock albuterol.
411	Section 12. Section 58-17b-1004 is enacted to read:
412	58-17b-1004. Authorization to dispense an epinephrine auto-injector and stock
413	albuterol pursuant to a standing order.
414	(1) Notwithstanding any other provision of this chapter, a pharmacist or pharmacy
415	intern may dispense an epinephrine auto-injector:
416	(a) (i) to a qualified adult for use in accordance with Title 26, Chapter 41, Emergency
417	Response for Life-threatening Conditions; or
418	(ii) to a qualified epinephrine auto-injector entity for use in accordance with Title 26,
419	Chapter 41, Emergency Response for Life-threatening Conditions;
420	(b) pursuant to a standing prescription drug order made in accordance with Section
421	58-17b-1005·

422	(c) without any other prescription drug order from a person licensed to prescribe an
423	epinephrine auto-injector; and
424	(d) in accordance with the dispensing guidelines in Section 58-17b-1006.
425	(2) Notwithstanding any other provision of this chapter, a pharmacist or pharmacist
426	intern may dispense stock albuterol:
427	(a) (i) to a qualified adult for use in accordance with Title 26, Chapter 41, Emergency
428	Response for Life-threatening Conditions; or
429	(ii) to a qualified stock albuterol entity for use in accordance with Title 26, Chapter 41,
430	Emergency Response for Life-threatening Conditions;
431	(b) pursuant to a standing prescription drug order made in accordance with Section
432	<u>58-17b-1005;</u>
433	(c) without any other prescription drug order from a person licensed to prescribe stock
434	albuterol; and
435	(d) in accordance with the dispensing guidelines in Section 58-17b-1006.
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436	Section 13. Section 58-17b-1005 is enacted to read:
436 437	Section 13. Section 58-17b-1005 is enacted to read: 58-17b-1005. Standing prescription drug orders for epinephrine auto-injectors
437	58-17b-1005. Standing prescription drug orders for epinephrine auto-injectors
437 438	<u>58-17b-1005.</u> Standing prescription drug orders for epinephrine auto-injectors and stock albuterol.
437 438 439 440	 58-17b-1005. Standing prescription drug orders for epinephrine auto-injectors and stock albuterol. (1) A physician acting in the physician's capacity as an employee of the Department of
437 438 439	58-17b-1005. Standing prescription drug orders for epinephrine auto-injectors and stock albuterol. (1) A physician acting in the physician's capacity as an employee of the Department of Health or as a medical director of a local health department may issue a standing prescription
437 438 439 440 441	58-17b-1005. Standing prescription drug orders for epinephrine auto-injectors and stock albuterol. (1) A physician acting in the physician's capacity as an employee of the Department of Health or as a medical director of a local health department may issue a standing prescription drug order authorizing the dispensing of an epinephrine auto-injector under Section
437 438 439 440 441 442	58-17b-1005. Standing prescription drug orders for epinephrine auto-injectors and stock albuterol. (1) A physician acting in the physician's capacity as an employee of the Department of Health or as a medical director of a local health department may issue a standing prescription drug order authorizing the dispensing of an epinephrine auto-injector under Section 58-17b-1004 in accordance with a protocol that:
437 438 439 440 441 442 443	58-17b-1005. Standing prescription drug orders for epinephrine auto-injectors and stock albuterol. (1) A physician acting in the physician's capacity as an employee of the Department of Health or as a medical director of a local health department may issue a standing prescription drug order authorizing the dispensing of an epinephrine auto-injector under Section 58-17b-1004 in accordance with a protocol that: (a) requires the physician to specify the persons, by professional license number,
437 438 439 440 441 442 443 444	58-17b-1005. Standing prescription drug orders for epinephrine auto-injectors and stock albuterol. (1) A physician acting in the physician's capacity as an employee of the Department of Health or as a medical director of a local health department may issue a standing prescription drug order authorizing the dispensing of an epinephrine auto-injector under Section 58-17b-1004 in accordance with a protocol that: (a) requires the physician to specify the persons, by professional license number, authorized to dispense the epinephrine auto-injector;
437 438 439 440 441 442 443 444 445	58-17b-1005. Standing prescription drug orders for epinephrine auto-injectors and stock albuterol. (1) A physician acting in the physician's capacity as an employee of the Department of Health or as a medical director of a local health department may issue a standing prescription drug order authorizing the dispensing of an epinephrine auto-injector under Section 58-17b-1004 in accordance with a protocol that: (a) requires the physician to specify the persons, by professional license number, authorized to dispense the epinephrine auto-injector; (b) requires the physician to review at least annually the dispensing practices of those
437 438 439 440 441 442 443 444 445 446	58-17b-1005. Standing prescription drug orders for epinephrine auto-injectors and stock albuterol. (1) A physician acting in the physician's capacity as an employee of the Department of Health or as a medical director of a local health department may issue a standing prescription drug order authorizing the dispensing of an epinephrine auto-injector under Section 58-17b-1004 in accordance with a protocol that: (a) requires the physician to specify the persons, by professional license number, authorized to dispense the epinephrine auto-injector; (b) requires the physician to review at least annually the dispensing practices of those authorized by the physician to dispense the epinephrine auto-injector;

450	the epinephrine auto-injector is dispensed;
451	(ii) a description of the epinephrine auto-injector dispensed; and
452	(iii) other relevant information; and
453	(d) is approved by the division by administrative rule made in accordance with Title
454	63G, Chapter 3, Utah Administrative Rulemaking Act, in collaboration with the Physicians
455	<u>Licensing Board created in Section 58-67-201</u> and the Board of Pharmacy.
456	(2) A physician acting in the physician's capacity as an employee of the Department of
457	Health or as a medical director of a local health department may issue a standing prescription
458	drug order authorizing the dispensing of the stock albuterol under Section 58-17b-1004 in
459	accordance with a protocol that:
460	(a) requires the physician to specify the persons, by professional license number,
461	authorized to dispense the stock albuterol;
462	(b) requires the physician to review at least annually the dispensing practices of those
463	authorized by the physician to dispense the stock albuterol;
464	(c) requires those authorized by the physician to dispense the stock albuterol to make
465	and retain a record of each dispensing, including:
466	(i) the name of the qualified adult or qualified stock albuterol entity to whom the stock
467	albuterol is dispensed;
468	(ii) a description of the stock albuterol dispensed; and
469	(iii) other relevant information; and
470	(d) is approved by the division by administrative rule made in accordance with Title
471	63G, Chapter 3, Utah Administrative Rulemaking Act, in collaboration with the Physicians
472	Licensing Board created in Section 58-67-201 and the board.
473	Section 14. Section 58-17b-1006 is enacted to read:
474	58-17b-1006. Guidelines for dispensing an epinephrine auto-injector and stock
475	albuterol.
476	(1) A pharmacist or pharmacy intern who dispenses an epinephrine auto-injector under
477	this part shall, at a minimum, provide patient counseling to the qualified adult or qualified

478	epinephrine auto-injector entity to whom the epinephrine auto-injector is dispensed regarding:
179	(a) the appropriate administration and storage of the epinephrine auto-injector;
480	(b) potential side effects and risks of the epinephrine auto-injector; and
481	(c) when to seek emergency medical attention.
182	(2) A pharmacist or pharmacy intern who dispenses stock albuterol under this part
483	shall, at a minimum, provide patient counseling to the qualified adult or qualified stock
184	albuterol entity to whom the stock albuterol is dispensed regarding:
485	(a) the appropriate administration and storage of the stock albuterol;
486	(b) potential side effects and risks of the stock albuterol; and
187	(c) when to seek emergency medical attention.
488	Section 15. Section 58-17b-1007 is enacted to read:
189	58-17b-1007. Limited civil liability.
490	(1) A physician who issues a standing prescription drug order in accordance with
491	Subsection 58-17b-1005(1) is not liable for any civil damages for acts or omissions resulting
192	from the dispensing of an epinephrine auto-injector under this part.
193	(2) A physician who issues a standing prescription drug order in accordance with
194	Subsection 58-17b-1005(2) is not liable for any civil damages for acts or omissions resulting
195	from the dispensing of stock albuterol under this part.
196	Section 16. Section 58-37f-201 is amended to read:
197	58-37f-201. Controlled substance database Creation Purpose.
198	(1) There is created within the division a controlled substance database.
199	(2) The division shall administer and direct the functioning of the database in
500	accordance with this chapter.
501	(3) The division may, under state procurement laws, contract with another state agency
502	or a private entity to establish, operate, or maintain the database.
503	(4) The division shall, in collaboration with the board, determine whether to operate
504	the database within the division or contract with another entity to operate the database, based
505	on an analysis of costs and benefits.

506	(5) The purpose of the database is to contain:
507	(a) the data described in Section 58-37f-203 regarding [every prescription for a
508	controlled substance dispensed in the state to any individual other than an inpatient in a
509	licensed health care facility] prescriptions for dispensed controlled substances;
510	(b) data reported to the division under Section 26-21-26 regarding poisoning or
511	overdose;
512	(c) data reported to the division under Subsection 41-6a-502(4) or 41-6a-502.5(5)(b)
513	regarding convictions for driving under the influence of a prescribed controlled substance or
514	impaired driving; and
515	(d) data reported to the division under Subsection 58-37-8(1)(e) or 58-37-8(2)(j)
516	regarding certain violations of the Utah Controlled Substances Act.
517	(6) The division shall maintain the database in an electronic file or by other means
518	established by the division to facilitate use of the database for identification of:
519	(a) prescribing practices and patterns of prescribing and dispensing controlled
520	substances;
521	(b) practitioners prescribing controlled substances in an unprofessional or unlawful
522	manner;
523	(c) individuals receiving prescriptions for controlled substances from licensed
524	practitioners, and who subsequently obtain dispensed controlled substances from a drug outlet
525	in quantities or with a frequency inconsistent with generally recognized standards of dosage for
526	that controlled substance;
527	(d) individuals presenting forged or otherwise false or altered prescriptions for
528	controlled substances to a pharmacy;
529	(e) individuals admitted to a general acute hospital for poisoning or overdose involving
530	a prescribed controlled substance; and
531	(f) individuals convicted for:

(i) driving under the influence of a prescribed controlled substance that renders the

individual incapable of safely operating a vehicle;

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S.B. 145 **Enrolled Copy** 534 (ii) driving while impaired, in whole or in part, by a prescribed controlled substance; or 535 (iii) certain violations of the Utah Controlled Substances Act. 536 Section 17. Section **58-37f-203** is amended to read: 537 58-37f-203. Submission, collection, and maintenance of data. 538 (1) (a) The division shall implement on a statewide basis, including non-resident 539 pharmacies as defined in Section 58-17b-102, the following two options for a pharmacist to 540 submit information: 541 (i) real-time submission of the information required to be submitted under this part to 542 the controlled substance database; and 543 (ii) 24-hour daily or next business day, whichever is later, batch submission of the information required to be submitted under this part to the controlled substance database. 544 545 (b) (i) On and after January 1, 2016, a pharmacist shall comply with either: 546 (A) the submission time requirements established by the division under Subsection 547 (1)(a)(i); or (B) the submission time requirements established by the division under Subsection 548 549 (1)(a)(ii).550 (ii) Prior to January 1, 2016, a pharmacist may submit information using either option 551 under this Subsection (1). 552 (c) The division shall comply with Title 63G, Chapter 6a, Utah Procurement Code. 553 (2) (a) The pharmacist-in-charge and the pharmacist of the drug outlet where a 554 controlled substance is dispensed shall submit the data described in this section to the division 555 in accordance with:

- 556 (i) the requirements of this section;
- 557 (ii) the procedures established by the division;
- (iii) additional types of information or data fields established by the division; and
- (iv) the format established by the division.
- (b) A dispensing medical practitioner licensed under Chapter 17b, Part 8, Dispensing
 Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy, shall comply with

the provisions of this section and the dispensing medical practitioner shall assume the duties of the pharmacist under this chapter.

- (3) (a) [The] Except as provided in Subsection (3)(b), the pharmacist-in-charge and the pharmacist described in Subsection (2)(b) shall, for each controlled substance dispensed by a pharmacist under the pharmacist's supervision [other than those dispensed for an inpatient at a health care facility], submit to the division any type of information or data field established by the division by rule in accordance with Subsection (6) regarding:
- (i) each controlled substance that is dispensed by the pharmacist or under the pharmacist's supervision; and
 - (ii) each noncontrolled substance that is:

- (A) designated by the division under Subsection (8)(a); and
- (B) dispensed by the pharmacist or under the pharmacist's supervision.
- (b) Subsection (3)(a) does not apply to a drug that is dispensed for [an inpatient] administration to, or use by, a patient at a health care facility, including a patient in an outpatient setting at the health care facility.
- (4) An individual whose records are in the database may obtain those records upon submission of a written request to the division.
- (5) (a) A patient whose record is in the database may contact the division in writing to request correction of any of the patient's database information that is incorrect. The patient shall provide a postal address for the division's response.
- (b) The division shall grant or deny the request within 30 days from receipt of the request and shall advise the requesting patient of its decision by mail postmarked within 35 days of receipt of the request.
- (c) If the division denies a request under this Subsection (5) or does not respond within 35 days, the patient may submit an appeal to the Department of Commerce, within 60 days after the postmark date of the patient's letter making a request for a correction under this Subsection (5).
 - (6) The division shall make rules, in accordance with Title 63G, Chapter 3, Utah

590	Administrative Rulemaking Act, to establish submission requirements under this part,
591	including:
592	(a) electronic format;
593	(b) submission procedures; and
594	(c) required information and data fields.
595	(7) The division shall ensure that the database system records and maintains for
596	reference:
597	(a) the identification of each individual who requests or receives information from the
598	database;
599	(b) the information provided to each individual; and
600	(c) the date and time that the information is requested or provided.
601	(8) (a) The division, in collaboration with the Utah Controlled Substance Advisory
602	Committee created in Section 58-38a-201, shall designate a list of noncontrolled substances
603	described in Subsection (8)(b) by rule made in accordance with Title 63G, Chapter 3, Utah
604	Administrative Rulemaking Act.
605	(b) To determine whether a prescription drug should be designated in the schedules of
606	controlled substances under this chapter, the division may collect information about a
607	prescription drug as defined in Section 58-17b-102 that is not designated in the schedules of
608	controlled substances under this chapter.
609	Section 18. Effective date.
610	(1) Except as provided in Subsection (2), this bill takes effect on May 12, 2020.
611	(2) The actions affecting the following sections take effect on July 1, 2020:
612	(a) Section 26-41-102;
613	(b) Section <u>26-41-105;</u>
614	(c) Section 58-17b-1001;
615	(d) Section <u>58-17b-1002;</u>
616	(e) Section 58-17b-1003;
617	(f) Section 58-17b-1004:

618	(g) Section 58-17b-1005;
619	(h) Section 58-17b-1006; and
620	(i) Section 58-17b-1007.